

BRUCE A. CHERNOF, M.D.
Acting Director and Chief Medical Officer

JOHN R. COCHRAN, III Chief Deputy Director

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COUNTY OF LOS ANGELES DEPARTMENT OF HEALTH SERVICES 313 N. Figueroa, Los Angeles, CA 90012 (213) 240-8101

February 23, 2006

The Honorable Board of Supervisors County of Los Angeles 383 Kenneth Hahn Hall of Administration 500 West Temple Street Los Angeles, California 90012

Dear Supervisors:

MEMORANDUM OF UNDERSTANDING WITH THE UNITED STATES DEPARTMENT OF THE NAVY FOR MEDICAL TRAINING

(1st District) (3 Votes)

IT IS RECOMMENDED THAT YOUR BOARD:

Approve and instruct the Acting Director of Health Services, or his designee, to sign a Memorandum of Understanding (Exhibit I) between the United States Department of the Navy and the County of Los Angeles to authorize a reciprocal exchange of residents between the Naval Medical Center, San Diego, California and LAC+USC Healthcare Network, in the medical field of Oral/Maxillofacial Surgery, with all residents receiving their training under the direct supervision of the respective hosting institution's physicians, with no exchange of money between the parties, effective upon date of Board approval and remaining in effect until terminated by either party.

PURPOSE/JUSTIFICATION OF THE RECOMMENDED ACTION:

The purpose of the recommended action is to authorize a reciprocal exchange of residents between the Naval Medical Center, San Diego, California (NMCSD) and LAC+USC Healthcare Network (LAC+USC) to receive medical training in the field of Oral/Maxillofacial Surgery, under the direct supervision and instruction of the respective hosting institution's physicians, with no exchange of money between the parties.

Gloria Molina First District

Yvonne Brathwaite Burke Second District

> Zev Yaroslavsky Third District

Don Knabe Fourth District

Michael D. Antonovich Fifth District The Honorable Board of Supervisors February 23, 2006 Page 2

FISCAL IMPACT/FINANCING:

There is no additional cost to the County.

FACTS AND PROVISIONS\LEGAL REQUIREMENTS:

For a number of years, the County has entered into affiliation agreements with a variety of educational institutions. The agreements are intended to allow the students to obtain observational and practical clinical experience in County facilities. The County benefits from receiving the assistance of additional personnel in the provision of patient care at no cost to the County. The County has entered into similar agreements with the U. S. Departments of the Navy, Army, and Air Force involving training in different medical fields and at different County medical facilities.

The recommended Memorandum of Understanding (MOU) is the first medical training agreement to allow a reciprocal exchange of residents between the County and a U.S. Armed Forces medical facility. Under the recommended MOU, the Navy will assign medical officers to LAC+USC to receive training in the field of Oral/Maxillofacial Surgery, and the County will assign residents to receive training in Oral/Maxillofacial Surgery at NMCSD. The number and assignment of trainees will be mutually agreed upon before the beginning of each training period.

The MOU will benefit the County by permitting NMCSD medical officers, who are physicians, to assist in providing patient care to County patients under County supervision. Additionally, LAC+USC's residents will have access to the unique training opportunities available at NMCSD.

The Navy medical trainees will be under official Navy orders assigning them to duty at LAC+USC, and County physicians will be responsible for the instruction and supervision of the Navy trainees during their training experience. While at LAC+USC, the Navy trainees will adhere to all applicable County rules and regulations, and will be provided with appropriate information regarding the County's Risk Management Program. LAC+USC residents assigned to NMCSD will be under the supervision of NMCSD officials and will be subject to, and required to abide by, all of NMCSD's rules and applicable regulations.

The Navy personnel assigned to LAC+USC will be prohibited from receiving any payment other than their military pay and allowances. LAC+USC will provide reasonable classroom, conference room, office, and sleeping and bathroom facilities during the training periods.

Under the provisions of the Federal Tort Claims Act, the Federal Government is liable for any negligent or wrongful acts or omissions of Navy employees committed while acting within the scope of their duties performed pursuant to the MOU. The County will be responsible for providing professional liability (malpractice) coverage for its residents while such residents are at NMCSD. Neither the County nor the United States Navy is agreeing to indemnify the other. The liability provisions of the MOU have been approved by the Chief Administrative Office, Risk Management Operations.

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The term of the recommended MOU is effective upon Board approval and shall remain in effect without further action unless terminated by either party with the provision of 30 days advance written notice.

The United States Navy requested the agreement using their MOU format, and therefore, the MOU does not include the usual County provisions.

Attachment A provides additional information.

County Counsel has approved the MOU (Exhibit I) as to use and form.

CONTRACTING PROCESS:

It is not appropriate to solicit a medical training agreement.

IMPACT ON CURRENT SERVICES (OR PROJECTS):

LAC+USC will benefit by having its Oral/Maxillofacial Surgery staff augmented by NMCSD medical officers, and by having access to the unique training opportunities available at NMCSD.

When approved, this Department requires three signed copies of the Board's action.

Respectfully submitted,

Bruge A. Chernoff, M.D.

Acting Director and Chief Medical Officer

BAC:pps BLETED4195.pps.wpd

Attachment (1)

c: Chief Administrative Officer

County Counsel

Executive Officer, Board of Supervisor

SUMMARY OF AGREEMENT

1. TYPE OF SERVICE:

Oral/Maxillofacial Medical Training

2. AGENCY ADDRESS AND CONTACT PERSON:

Naval Medical Center 34800 Bob Wilson Drive, Box 117 San Diego, California 92134-5000 Attention: Commander B. G. Brannman

Telephone: (619) 532-7936

3. TERM:

The MOU will become effective upon Board approval and remain in effect without further action unless terminated by either party with the provision of 30 days advance written notice.

4. FINANCIAL INFORMATION:

There is no cost to the County.

5. ACCOUNTABLE FOR MONITORING AND EVALUATION:

Pete Delgado, Chief Executive Officer LAC+USC Healthcare Network

6. APPROVALS:

Clinical Affairs and Affiliations: William Loos, M.D., Acting Senior Medical Officer

Finance: Gary W. Wells, Director

Contracts and Grants Division: Cara O'Neill, Chief

County Counsel: Elizabeth Friedman, Senior Deputy County Counsel

BLETCD4195.PPS

MEMORANDUM OF UNDERSTANDING BETWEEN NAVAL MEDICAL CENTER, SAN DIEGO AND COUNTY OF LOS ANGELES

- 1. This agreement is entered into by and between Naval Medical Center, 34800 Bob Wilson Drive, San Diego, California 92134-5000, hereinafter referred to as "MTF", and the County of Los Angeles, hereafter called the "Affiliating Institution", for itself, and the Los Angeles County/University of Southern California Healthcare Network, Los Angeles, CA (LAC + USC Healthcare Network) only.
- 2. The MTF and the administrators of the Affiliating Institution have established an approved professional program that has been recognized, accredited, or certified by the appropriate accrediting agencies, as applicable. The specific nature of this program is to train Navy Oral/Maxillofacial residents and Los Angeles County, University of Southern California Oral/Maxillofacial Surgery residents while using the facilities at the MTF and the affiliating institution.
- 3. The MTF and the Department of the Navy will benefit by participating in a well-diversified professional program which will enable its trainees to use the clinical facilities of the affiliating institution to receive their clinical experience.
- 4. The Affiliating Institution will benefit by participating in a well-diversified professional program which will enable its trainees to use the clinical facilities at the MTF to receive their clinical experience.
- 5. The parties acknowledge and agree to the following:
- a. As used in this agreement, "employer-institution" refers to the institution that pays the trainee's salary. "Supervising-institution" shall refer to that institution to which the trainee is assigned for training.
- b. When trainees of either party are participating under this agreement at the clinical facilities of the supervising-institution, the trainees will be under the supervision of facility officials of the supervising-institution and will be subject to and be required to abide by, all of the supervising-institution's rules and applicable regulations. It is understood that Navy trainees will be subject to and required to abide by all civilian facility rules and applicable regulations, except where compliance would be inconsistent with Federal statutes, regulations, or any other law binding members of the U.S. Navy
- c. There will be no compensation paid to trainees of either party to this agreement for participating in this program, other than what compensation the trainees receive from their employerinstitution. The use of either party's facilities is for the

training described in this agreement and no compensation will be paid for any incidental work benefits that accrue to either party. It is agreed and understood that the supervising-institution, may generate bills for services rendered by the trainees. Proceeds from these bills will become the exclusive property of the supervising-institution, and the employer-institution shall have no right or claim to such proceeds. Notwithstanding the above, as required by 32 C.F.R. §199.6(a)(3), the Affiliating Institution cannot bill under the TRICARE Program for the services rendered by U.S. Navy trainees.

- d. The program described in this agreement is not intended to displace employees or impair existing contracts for services.
- e. The number and assignment of trainees will be mutually agreed upon between the MTF and the Affiliating Institution before the beginning of each training period. Each of the parties specifically reserves the right to refuse any trainee's acceptance into a program conducted at their respective facility or to bar any participant involved in a training program under this agreement when it is determined that further participation would not be in the best interest of either party.
- f. Neither party will use the name of the other party's institution or trainees' or faculty members' names in publicity or advertising media without the express written consent of the institution. However, the existence and scope of the program may be known.
- g. Neither party of this agreement nor their trainees will publish any materials developed as the result of their clinical experience until such publication has been approved for release, in writing, by the MTF and the Affiliating Institution.

h. Health Information Privacy

Pursuant to DODINST 6025.18, Privacy of Individually Identifiable Health Information in DoD Health Care Programs, December 19, 2002, DoD 6025.18-R, and 45 C.F.R. Parts 160 and 164, the parties agree to enter into a Business Associate Agreement, Appendix A of this MOU.

6. For all training programs under this agreement the supervising-institution specifically agrees to:

- a. Make available the clinical and related facilities needed for training under this agreement.
- b. Arrange schedules that will not conflict with other educational programs and the orderly operation of the institution.
- c. Designate an official to coordinate trainees' clinical learning experience. This will involve planning with faculty or

staff members for the assignment of trainees to specific clinical cases and experiences, including their attendance at selected conferences, clinics, courses, and programs conducted under the direction of the institution.

- d. Provide reasonable classroom, conference, office, storage, dressing and locker room space for participating trainees and their faculty or staff supervisors.
- e. Permit, on reasonable request, the inspection of clinical and related facilities by agencies charged with the responsibility for accreditation of the employer-institution's educational programs.
- f. Provide emergency medical and dental treatment to trainees while in the medical facility for training to the extent it is available. The cost of such treatment will be assessed according to the rendering institution's applicable rules and regulations and will be paid for by the trainee or the respective employerinstitution.
- g. Arrange the necessary access to the clinical facilities, including necessary parking or base permits and access to the administrative privileges typically enjoyed by the supervising-institution's trainees.

7. Indemnification and Insurance:

- a. The civilian employer-institution agrees to provide professional liability (malpractice) coverage, in amounts that are reasonable and customary in the community for the appropriate specialty, covering liability for personal injury and property damage, including expense of defense of any such liability claims or actions, resulting from participation by their civilian trainees or faculty under this agreement. The civilian employer-institution's liability coverage may come from any source, but shall clearly cover their faculty and trainees while participating under this agreement.
- b. U.S. Navy trainee affected by this agreement, assigned to the training institution(s), under orders issued by the U.S. Navy, remains an employee of the United States and performs duties within the course and scope of their federal employment. Consequently, the provisions of the Federal Tort Claims Act (title 28, U.S.C., sections 1346 (b), 2671-2680) including its defenses and immunities, will apply to allegations of negligence or wrongful acts or omissions by the Navy trainees committed while acting within the scope of their duties performed pursuant to this agreement.
 - c. The Affiliating Institution, a political sub-division of

the state of California, in accordance with California Government Code Section 959-991.2, County Code Chapter 5.32, and Articles 1 and 2 of this Los Angeles County charter, is authorized to self-insure for its liability. This self-insurance includes coverage for legal liability and defense costs for claims asserted by third parties for bodily injury and property damage, including general and professional liability (malpractice), and shall satisfy the Affiliating Institution's Indemnification obligations under this MOU. Each party agrees not to seek indemnification from the other party or its trainees for any settlement, verdict or judgment resulting from any claim or lawsuit arising out of the performance of the trainee's professional duties while acting under the control of the supervising-institution and its employees.

- d. In the event the employer-institution is sued by a plaintiff seeking to hold it vicariously liable for negligent acts of its trainee while performing duties at the supervisinginstitution, the employer-institution shall make all legal defenses including the terms of this agreement to defend the However, neither the employer-institution nor the supervising-institution shall seek indemnification from any trainee acting within course and scope of training. When the supervising-institution settles or pays any claims against it involving trainees of the other institution, the supervisinginstitution shall obtain as broad a release as possible from the plaintiff or claimant to provide the employer-institution protection from further claims. Each institution agrees to notify the other when a claim is received and to cooperate to the fullest extent possible with the other institution in preparing for conducting the defense of any malpractice claim involving the trainees.
- 8. The parties understand and agree that consistent with the Federal statute and the Federal Acquisition Regulation (FAR), the U.S. Navy trainee performing under this Agreement is not required to satisfy the State of California temporary or permanent licensure requirements. Under the provision of 10 U.S.C. §§1094(d)(1) and (2), the U.S. Navy trainee has portability of his/her healthcare professional licenses.
- a. Specifically, 10 United States Code §§10984(d)(1)
 and(2)provide:
- (1) Notwithstanding any law regarding the licensure of a US.S. Navy trainee, a healthcare professional described in paragraph (2), may practice the health profession or professions of the health-care professional in any state, District of Columbia, or a Commonwealth, territory, or possession of the U.S., regardless of whether the practice occurs in a healthcare facility of the Department of Defense, a civilian facility affiliated with the Department of Defense, or any other location authorized by the Secretary of Defense.

- (2) A healthcare professional referred to in paragraph(2) is a member of the armed forces who:
- (a) Has a current license to practice medicine, osteopathic medicine, dentistry, or another health profession.
- (b) Is performing authorized duties for the Department of Defense.
- b. Naval Medical Center, San Diego, in accordance with the requirements of 10 U.S.C. $\S\S1094(4)(d)(1)$ and (2), authorizes the training location and duties of the U.S. Navy trainee at LAC + USC Healthcare Network, as they will be performing their duties under military orders issued by the U.S. Navy.
- 9. Notice hereunder shall be in writing and sent to the parties at the following addresses and to the attention of the persons names. The Director of the County Department of Health Services or his delegatee has the authority to execute all notices to be given by County under this agreement. Addresses and person to be notified may be changed by appropriate written notice.
- 1. Notices to the Federal government shall be addressed as follows:
 - (a) Commander
 Naval Medical Center
 Director for Medical Education
 34800 Bob Wilson Drive, Box 117
 San Diego, CA 92134-5000
 - (b) Director for Oral and Maxillofacial Surgery
 Residency Program
 34800 Bob Wilson Drive, Suite 206
 San Diego, CA 92134-1206
- 2. Notices to the Affiliating Institution shall be addressed as follows:
 - (a) LACUSC Healthcare Network
 Director, Office of Graduate Medical Education
 1200 No. State Street, Room 1102
 Los Angeles, CA 90033
 - (b) Department of Health Services Director, Office of Clinical and Medical Affairs 1200 No. Figueroa Street

Los Angeles, CA 90033

- (c) Department of Health Services Chief, Contracts and Grants Division 313 No. Figueroa Street Los Angeles, CA 90012
- 10. According to Navy instructions, each trainee from affiliating institution is required to sign a trainee agreement addendum containing the provisions of the sample attachment to this agreement.
- 11. It is expressly agreed that this written statement embodies the entire agreement of the parties regarding this affiliation, and no other agreements exist between the parties except as herein expressly set forth. Any changes or modifications to this agreement must be in writing and be signed by both parties.
- 12. The terms of this agreement will commence as of the date signed by both parties and will continue until completion of training or until terminated by either party. Either party may terminate this agreement with the provision of 30 days advance written notice to the other party. It is understood that the Chief, Bureau of Medicine and Surgery will have the right to terminate this affiliation agreement without notice at any time, if determined necessary to be in the interests of the Navy's mission requirements.

t	written notice to the other party. It Chief, Bureau of Medicine and Surgery cerminate this affiliation agreement if determined necessary to be in the mission requirements.	y will have the right to without notice at any ti
I 2 7 7	By G. BRANNMAN Rear Admiral (Lower Half) Senior Health Care Executive Jnited State Navy Commander Naval Medical Center San Diego, CA 92134-5000	Date 22 Dec 05
Affiliating Institution		
E	Bv	Date
	Bruce A. Chernof, M.D. Acting Director and Chief Medical	
Approved as to Contract Administration		
E	ByChief, Contracts and Grants Division	Date
•	6	

TRAINEE AGREEMENT ADDENDUM

In consideration of being allowed to use the facilities of the Naval Medical Center, San Diego per the Memorandum of Understanding between LAC + USC Healthcare Network and Naval Medical Center, San Diego, I agree to abide by the rules and instructions listed in the agreement. I am aware of the rules concerning automobile liability insurance, and, if I drive my private automobile on base, I will register it with base authorities and maintain the required liability insurance. I specifically agree and understand that I will receive no monetary compensation whatsoever from the United States for this training.

(Date) (Signature and typed name of trainee

APPENDIX A

PRIVACY OF PROTECTED HEALTH INFORMATION

(a) Definitions. As used in this Appendix:

<u>Business Associate</u> has the same meaning as the term "Business Associate" in 45 CFR 160.103.

<u>Covered Entity</u> has the same meaning as the term "Covered Entity" in 45 CFR 160.103.

 $\underline{Individual}$ has the same meaning as the term "individual" in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

<u>Privacy Rule</u> means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

<u>Protected Health Information</u> has the same meaning as the term "protected health information" in 45 CFR 164.501, limited to the information created or received by The Business Associate from or on behalf of The Covered Entity.

Required by Law has the same meaning as the term "required by law" in 45 CFR 164.501.

<u>Secretary</u> means the Secretary of the Department of Health and Human Services or his/her designee.

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in 45 CFR 160.103 and 164.501.

- (b) We have determined that both parties serve as employer and supervising institutions in this MOU. Consequently, in this MOU, both Naval Medical Center, San Diego and Affiliating Institution are Covered Entities as defined above; likewise, both Naval Medical Center, San Diego and Affiliating Institution are Business Associates as defined above.
- (c) The Business Associate agrees not to use or further disclose Protected Health Information other than as permitted or required by this Agreement or as Required by Law.
- (d) The Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected

Health Information other than as provided for by this Agreement.

- (e) The Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to the Business Associate of a use or disclosure of Protected Health Information by the Business Associate in violation of the requirements of this Agreement.
- (f) The Business Associate agrees to report to the Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement.
- (g) The Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by the Business Associate on behalf of the Covered Entity agrees to the same restrictions and conditions that apply through this Agreement to the Business Associate with respect to such information.
- (h) The Business Associate agrees to provide access, at the request of the Covered Entity, and in the time and manner designated by the Covered Entity to Protected Health Information in a Designated Record Set, to the Covered Entity or, as directed by the Covered Entity, to an Individual in order to meet the requirements under 45 CFR 164.524.
- (i) The Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR 164.526 at the request of the Covered Entity or an Individual, and in the time and manner designated by the Covered Entity.
- (j) The Business Associate agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by the Business Associate on behalf of, the Covered Entity, available to the Covered Entity, or at the request of the Covered Entity to the Secretary, in a time and manner designated by the Covered Entity or the Secretary, for purposes of the Secretary determining the Covered Entity's compliance with the Privacy Rule.
- (k) The Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for the Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.
- (1) The Business Associate agrees to provide to the Covered Entity or an Individual, in time and manner

designated by the Covered Entity, information collected in accordance with this Appendix of the Agreement, to permit the Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

General Use and Disclosure Provisions

Except as otherwise limited in this Agreement, the Business Associate may use or disclose Protected Health Information on behalf of, or to provide services to, the Covered Entity for the following purposes, if such use or disclosure of Protected Health Information would not violate the Privacy Rule or the Department of Defense Health Information Privacy Regulation if done by the Covered Entity:

Specific Use and Disclosure Provisions

- (a) Except as otherwise limited in this Agreement, the Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.
- (b) Except as otherwise limited in this Agreement, the Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are required by law, or the Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
- (c) Except as otherwise limited in this Agreement, the Business Associate may use Protected Health Information to provide Data Aggregation services to the Covered Entity as permitted by 45 CFR 164.504(e)(2)(i)(B).
- (d) Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1).

Obligations of the Covered Entity

Provisions for the Covered Entity to Inform the Business Associate of Privacy Practices and Restrictions

(a) Upon request the Covered Entity shall provide the Business Associate with the notice of privacy practices that

the Covered Entity produces in accordance with 45 CFR 164.520, as well as any changes to such notice.

- (b) The Covered Entity shall provide the Business Associate with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect the Business Associate's permitted or required uses and disclosures.
- (c) The Covered Entity shall notify the Business Associate of any restriction to the use or disclosure of Protected Health Information that the Covered Entity has agreed to in accordance with 45 CFR 164.522.

Permissible Requests by the Covered Entity

The Covered Entity shall not request the Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by the Covered Entity, except for providing Data Aggregation services to the Covered Entity and for management and administrative activities of the Business Associate as otherwise permitted by this Appendix.

Termination

- (a) Termination. A breach by the Business Associate of this Appendix, may subject the Business Associate to termination under any applicable default or termination provision of this Agreement.
 - (b) Effect of Termination.
- (1) If this Agreement has records management requirements, the records subject to the Appendix should be handled in accordance with the records management requirements. If this TAA does not have records management requirements, the records should be handled in accordance with paragraphs (2) and (3) below
- (2) If this Agreement does not have records management requirements, except as provided in paragraph (3) of this section, upon termination of this Agreement, for any reason, the Business Associate shall return or destroy all Protected Health Information received from the Covered Entity, or created or received by the Business Associate on behalf of the Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of the Business Associate. The Business Associate shall retain no copies of the Protected Health Information.
 - (3) If this Agreement does not have records

management provisions and the Business Associate determines that returning or destroying the Protected Health Information is infeasible, the Business Associate shall provide to the Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual Agreement of the Covered Entity and the Business Associate that return or destruction of Protected Health Information is infeasible, the Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as the Business Associate maintains such Protected Health Information.

Miscellaneous

- (a) Regulatory References. A reference in this Appendix to a section in the Privacy Rule means the section as in effect or as amended, and for which compliance is required.
- (b) Survival. The respective rights and obligations of Business Associate under the "Effect of Termination" provision of this Appendix shall survive the termination of this Agreement.
- (c) Interpretation. Any ambiguity in this Appendix shall be resolved in favor of a meaning that permits the Covered Entity to comply with the Privacy Rule.